ANAMAX

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852.

Re. Docket No 2002N-0273, Substances Prohibited From use in Animal Food or Feed

To Whom It May Concern:

We are writing this letter in reference to the above mentioned Docket on behalf of the Anamax Group of companies and its 350 employees at four locations in Wisconsin and Minnesota.

I along with members of the National Renderers Association have had the opportunity to meet personally with representatives of EPA, USDA, OMB and FDA to discuss our concerns with making any changes to the current feed rule that has been in place since 1997.

We continue to receive good news daily with the enhanced surveillance program having tested more than 534,879 cattle and finding, possibly, one indigenous cow that tested positive. This, along with the continued extraordinary compliance with the feed rule at greater than 99% begs the question; on what basis should any changes be made?

The original Harvard risk assessment showed that if there were 10 positive animals that happened to be rendered and continued into the animal feed chain due to a much lower compliance rate with the current rule, there may be a chance for 4 animals to develop BSE over a 20 year period. What we now hear touted by the Agency is that by removing the brain and spinal cord we have a 90% reduction in risk, which sounds wonderful, but in actuality reduces the potential from 4 animals to 1.

Taking the actual incidence of BSE into account based upon the test results, along with adjusting the possibility of BSE actually propagating with a 99% compliance rate with the feed ban makes the equation even more ridiculous. 90% of 0 is still 0.

FDA has always used science based rationale for its decision making. To begin deviating from that philosophy at this time is dangerous. It begins a slippery slope of rationalizing public perception or letting political pressures dictate policy. The feeling that "something needs to be done" is not sufficient. In fact, taking the reasoning that something needs to be done one step further, removal of the brain only would have the affect of decreasing risk

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over 60% and would have a much lower downstream affect on those affected by the rule. The problem is that neither of these options support OIE's recommendations yet both support the "we did something philosophy."

We are seeing borders opening at some of our major trading partners and continued discussion to open trade throughout the world. The proposed rule however does nothing to promote harmonization with Canada which is a much more critical concern to the future health of animal agriculture in North America.

The Agency will be receiving and reviewing the 2005 Rendering Industry Study by Informa Economics that will strongly support the concerns that our industry has expressed to FDA over the past two years. If the proposed rule is implemented, the perception of BSE will not be the problem; disposal, disease, enforcement and a major financial effect on a tremendous amount of people involved in animal agriculture will be the result.

We encourage the agency to update the Harvard Model, continue with the enhanced surveillance program and strictly enforce the current regulations. Please, take no further action.

Sincerely,

Michel Langenhorst
President and CEO